EC Declaration of Conformity

Name	Matter	Device Description
Qflow® (FS1028)	Polypropylene	Single-use sensor

Medical devices conform to the following standards:

EN ISO 10993-1:2009/AC: 2010: Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.
EN ISO 10993-5:2009: Biological evaluation of medical devices - Partie 5 : Tests for in vitro cytotoxicity
EN ISO 10993-10:2010: Biological evaluation of medical devices - Partie 10 : Tests for irritation and skin sensitization
NF EN ISO 14971:2013: Medical devices - Application of risk management to medical devices
NF EN 1041 + A1: 2013: Information supplied by the manufacturer of medical devices
EN ISO 15223-1:2016: Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General

I the undersigned, Marie-Ange DEREI, President of the FIM MEDICAL company located at 51 rue Antoine Primat Villeurbanne - FRANCE assure and declare that the medical devices listed above belong to class IIa (Rule 10) and satisfy the provisions of annex I (Essential Requirements), annex VI (Product Quality Assurance) and annex VII (Evaluation of Spirolyser® Q13 FF1037DTR100 technical file) of the 93/42/EEC directive and its local adaptation (Book V of the public health code).

The devices described above are covered by the EC Certificate n° 27671 delivered by LNE/G-MED, 1 rue Gaston Boissier, 75724 Paris Cedex 15.

Villeurbanne, 8 August 2018,
Marie-Ange DEREI

Président

CE
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